



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,010	12/31/2003	Zhihao Fang	SHE0059.00	5510
21968	7590	08/23/2006		
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER FIGUEROA, JOHN J	
			ART UNIT	PAPER NUMBER

1712

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/751,010	Applicant(s) FANG ET AL.	
	Examiner John J. Figueroa	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/23/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 11-14, drawn to a method for making a crosslinked polymer composition, classified in class 528, subclass 391.
- II. Claims 10 and 15-20, drawn to a compound and a crosslinked polymer composition comprising thereof, classified in class 525, subclass 54.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polymer derivative can be formed by attaching a thiol adduct to a water-soluble polymer to form a polymer-thiosulfate, oxidizing the thiol functional group to form a polymer-thiosulfonate compound, and subsequently crosslinking said polymer-thiosulfonate compound.
3. Because these inventions are independent or distinct for the reasons given above, have acquired a separate status in the art in view of their different classification and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Art Unit: 1712

4. During a telephone conversation with Mr. Mark A. Wilson on August 18, 2006, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and 11-14. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 10 and 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim limits the thiosulfonate polymer derivative to a "*multi-arm* thiosulfonate ester of a ... polymer." [Emphasis added.] It is unclear as to what the term "multi-arm" encompasses and how it limits said ester. In the specification, Applicant defines the polymers as "linear, branched, multi-arm or forked." (See, e.g., specification, page 11, lines 8-9 and 19-20) Thus, it would be confusing to

Art Unit: 1712

one skilled in the art as to how to distinguish a multi-armed polymer from either a "branched" polymer or a "forked" polymer.

8. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8 and 9 recite the limitation "said at least one *biologically* active agent" in line. [Emphasis added.] There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-4 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent Number (USPN) 3,301,831 to Orthner et al., hereinafter 'Orthner'.

Orthner discloses a process for preparing a thiosulfonate condensation product from a water-soluble thiosulfate, wherein the resultant thiosulfonate can be a water-

Art Unit: 1712

insoluble alkylthiosulfonate, or an arylthiosulfonate, having polysulfide bridges (thus, a "multi-armed", hydrogel-polysalt). (Col. 1, lines 22-58) The polythiosulfonate salt is subsequently condensed and crosslinked in an alcoholic solution at a pH of at least 8 and at a temperature ranging from 0 to at least 150°C, without a crosslinking agent or catalyst. (Col. 2, line 47 to col. 3, line 8)

In Example 10, Orthner discloses a resultant water-insoluble thiosulfonate-polyester resin (hydrogel) that was formed under the aforementioned conditions and that remained stable even after heating for ten minutes. (Col. 6, line 73 to col. 7, line 31)

Although Orthner does not expressly disclose the amount of thiosulfonate present in the resultant hydrogel composition, because the instant claims encompass the same thiosulfonate hydrogel composition, made by the same process, as does Orthner, then both thiosulfonate hydrogel compositions must inherently possess the same physical properties, such as the concentration/density of thiosulfonate in the resultant hydrogel composition.

Thus, the claims are anticipated by Orthner.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1712

12. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orthner in view of USPN 6,774,180 B2 to Kozlowski et al., hereinafter 'Kozlowski'.

Orthner was discussed above in paragraph #10. Orthner further discloses that the thiosulfonate hydrogel resin can be used as insulating material and for finishing of textiles. (Col. 3, lines 38-43)

Although Orthner discloses polymeric thiosulfonates, Orthner does not explicitly disclose the polymer composition having the formula recited in claim 5, or a biologically active agent attached to the thiosulfonate polymer derivative.

Kozlowski teaches a high molecular weight "pegylated" polymer (containing polyethylene glycol) having a linking moiety (X) and a functional group (Y) that is attached to a biological active agent; wherein any of the moieties may be covalently attached; and wherein Y can be a thiosulfonate functional group; and wherein said formula is in accordance with that recited in instant claim 5. (Col. 8, line 42 to col. 9, line 22; col. 21, lines 17-30 and 51-57)

Kozlowski further teaches that these high molecular weight pegylated polymeric derivatives can be readily formed without large number of reactions, thus producing less polymeric impurities, thereby providing for a more cost-efficient manufacturing process.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time that the claimed invention was made to use the pegylated-polymeric taught by Kozlowski as the polymer component in Orthner's process of making an insulation/textile products containing a polythiosulfonate resin. It would have been

Art Unit: 1712

obvious to one in skilled in the art to do so to attain a resultant process of manufacturing that is more cost-effective and environmentally friendly as taught by Kozlowski.

Conclusion

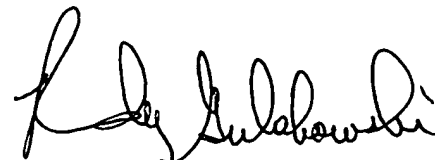
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John J. Figueroa whose telephone number is (571) 272-8916. The examiner can normally be reached on Mon-Thurs & alt. Fri 8:00-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JJF/RAG

A handwritten signature in black ink, appearing to read "Randy Gulakowski". The signature is fluid and cursive, with the first name "Randy" and last name "Gulakowski" clearly distinguishable.

RANDY GULAKOWSKI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700